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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,536	02/10/2004	James J. Rudnick	760-84 CON 4	6703
23869	7590	06/01/2007		
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/775,536

Applicant(s)

RUDNICK ET AL.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Request for Continued Examination

The request 4/27/2007 on for a Request for Continued Examination under 37 CFR 1.114 based on Application No. 10775536 is acceptable and a RCE has been established.

Status of the Claims

Previously pending claims 19-25 have been cancelled and claims 61-72 have been newly presented.

Applicant is reminded that claims 1-53 were not the originally filed claims of parent application SN 09/977823. Accordingly, applicant records and comments should be corrected to be consistent with the subject matter of the parent application.

Applicant responded:

Initially, it is noted that the Examiner indicates that the original claims filed on February 10, 2004 included claims 1-18. During subsequent prosecution, claims numbering 19-53 have been added. For clarity, Applicant filed the current claims in the present application as claims 54-60. While Applicant acknowledges that the original application was filed with 18 claims, the claim numbering used herein is believed to avoid any confusion with any previous related applications.

For clarity of the record, claims 19-53 have not been officially added by an amendment during the prosecution of this application. In order to be consistent with the numbering of the claims in the instant application, claims 54-60 were renumbered as 19-25, respectively. And newly presented claims 61-72 have been renumbered as 26-38, respectively.

Response to Arguments

Applicant's arguments filed 4/27/2007 have been fully considered.

The claims submitted herein are believed to be fully supported by Applicant's priority application.

Therefore, it is submitted that U.S. Patent No. 6,517,570 to Lau et al. is not citable against the claims. Moreover, it is respectfully submitted that the claims define patentably over the art of record. The application is therefore believed to be in condition for allowance

The examiner notes that applicant failed to provide information directed to the language in the original specification that supports the newly presented claims 61-72 (now claims 26-38).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Sole independent claim 26 requires the function of "minimize tissue ingrowth between the waves". This function is not clearly supported in the original specification. On page 2 of the specification, the language directed to tissue ingrowth is as follows:

situations, such as when the stent is employed in the urogenital or bile tract, it is also desirable to inhibit tissue ingrowth through the stent. Such ingrowth through the stent could have a tendency to reclose or

occlude the open lumen. The open spaces between the wires forming the stent, while facilitating flexibility and expansion, have a tendency to allow such undesirable tissue ingrowth

The language in this passage is directed to inhibit tissue ingrowth and not "minimize tissue ingrowth" as is set forth in the claim. While the scope may be similar, they are not necessarily equivalent and synonymous as desired by applicant. In fact the only portion of the specification that deals with the concept of "minimize" is found in column 4. The language is directed to minimizing the pitch or spacing between the adjacent winding and not to tissue ingrowth.

As can be seen with respect to FIG. 5, the peaks 31 of the waves of longitudinally adjacent windings 24 are each linearly aligned so that each wave is stacked or nested within the next adjacent wave. In optimum configuration, the spacing or pitch 26 between each longitudinally successive winding 24 is constructed to be minimal. However, nesting or stacking does occur where the pitch or spacing between longitudinally adjacent windings 24 is less than 2A i.e. the peak-to-peak amplitude. As long as the pitch remains less than 2A each longitudinally adjacent winding 24 will be nested within the wave formed by the previously formed winding 24. By minimizing the pitch or spacing 26 between adjacent windings 24, the open space between windings may be minimized. The particular wave-like pattern imparted to wire 22 as shown in FIG. 4 allows particularly tight stacking of longitudinally adjacent windings.

Claims 26-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting tissue ingrowth, does not reasonably provide enablement for "minimize tissue ingrowth". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. There is nothing in the specification that clearly defines the metes and bounds of the language "minimize tissue ingrowth". It is not clear what would be an acceptable range

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concerning the amount of tissue ingrowth between the spacings. Applicant's specification is silent to what constitutes a minimum value for tissue ingrowth. While the specification intends to inhibit tissue ingrowth, the amount of inhibition is not clearly set forth. As such, one with ordinary skill in the art would not know how to make or use the invention to minimize tissue ingrowth between the spacings.

Since this limitation does not find clear support to the chain of applications back to the earliest parent, the subject matter, as claimed, does not enjoy benefit of the earlier filing dates.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10,18,26,29,32,72,81 of U.S. Patent No. 6319277; and claims 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10 of U.S. Patent No. 5575816. Although the conflicting claims are not identical, they are not patentably distinct from each other because newly presented independent claim 26 is a broader species than the narrower species of claim 1 in US Patent 6319277. Although the functional language of the nested stent is not clearly defined in the claims as providing means for minimizing tissue ingrowth, the configuration of the claimed stent in the parent and the instant application do not differ and therefor would provide the function of minimizing (i.e. inhibiting) tissue ingrowth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

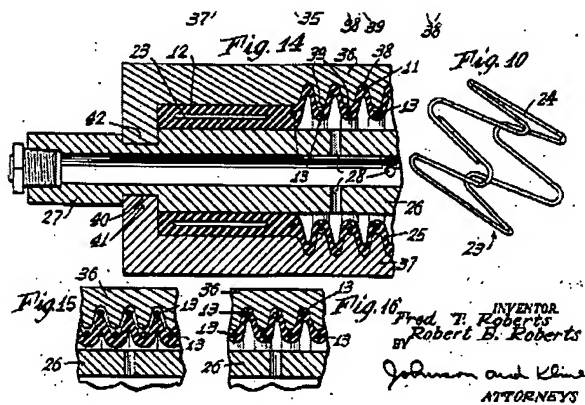
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 26,65,66,68,69 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roberts, et al [2780274].

Roberts, et al discloses a tubular device having wire defining a plurality of nested wire waves and a non-porous cover extending along the length of the tubular device. While the device is not intended for intraluminal applications, the resulting structure would provide the function of not allowing free tissue ingrowth through the cover and through the wire.



See column 3, lines 30+.

Also, in accordance with the present invention, it may be desired to provide the attaching portions 12 of the hose with a resilient reinforcing means. In the preferred form of the invention this comprises a relatively wide band of hard resilient material 23 which extends around the attaching portion and is embedded therein.

While the broad reinforcing means may be made in many ways, it is herein preferred to form it by bending a spring wire 24 in zigzag or sinusoidal relation and wrapping it into an annular member as shown in Fig. 10. When this is embedded in the attaching portion, it will be seen that the wires of the band extend longitudinally of the axis of the hose for a substantial distance along the attaching portion. It is to be understood that if a very broad reinforcing band is required, several wire bands can be positioned side by side with the zigzag portions nested to provide the additional reinforcing area.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.


Claims 26-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau, et al [6517570]. The claimed subject matter does not enjoy the benefits of an earlier filing date and therefor are anticipated by Lau, et al. Lau et al was issued on 2/11/2003 and has established priority back to 8/31/1994

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
5/18/2007